

**AMENDMENT**  
**USSN 09/975,418**

**IN THE CLAIMS:**

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1. (previously amended) An inhalable powder comprising 0.04 to 0.8% of tiotropium in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.
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2. (previously amended) An inhalable powder according to claim 1, wherein the tiotropium is present in the form of the chloride, bromide, iodide, methanesulphonate, para-toluenesulphonate or methyl sulphate thereof.
  3. (previously amended) An inhalable powder comprising between 0.048 and 0.96% of tiotropium bromide in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.
  4. (previously amended) An inhalable powder comprising between 0.05 and 1% of tiotropium bromide monohydrate in admixture with a physiologically acceptable excipient, wherein the

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excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient with an average particle size of 1 to 9  $\mu\text{m}$ , the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient.

5. (previously amended) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 17 to 50  $\mu\text{m}$  and finer excipient with an average particle size of 2 to 8  $\mu\text{m}$ .

6. (previously amended) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the proportion of finer excipient in the total amount of excipient is 3 to 15%.

7. (previously amended) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the tiotropium used has an average particle size of 0.5 to 10  $\mu\text{m}$ .

8. (previously amended) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein one or more monosaccharides, disaccharides, oligo- or polysaccharides, polyalcohols, salts thereof, or mixtures thereof are used as the excipients.

9. (previously amended) An inhalable powder according to claim 8, wherein glucose, arabinose, lactose, saccharose, maltose, dextrane, sorbitol, mannitol, xylitol, sodium chloride, calcium

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carbonate or mixtures thereof are used as the excipients.

10. (previously amended) An inhalable powder according to claim 9, wherein glucose or lactose or mixtures thereof are used as the excipients.

11. (original) A process for preparing an inhalable powder according to one of claims 1 to 4, comprising: (a) mixing coarser excipient fractions with finer excipient fractions to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium.

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12. (cancelled)

13. (original) A method of treating a disease that is responsive to the administration of tiotropium, comprising administering to a host in need thereof an inhalable powder according to one of claims 1 to 4 or 12.

14. (original) A method according to claim 13, wherein the disease is asthma or COPD.

15. (original) An inhaler capsule containing an inhalable powder according to one of claims 1 to 4 or 12.

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16. (original) An inhalette capsule containing from 3 to 10 mg of inhalable powder according to one of claims 1 to 4 or 12.

17. (original) An inhalette capsule according to claim 16, containing between 1.2 and 80 µg of tiotropium.

18. (previously added) An inhalable powder according to claim 4 comprising 0.1 to 0.8% of tiotropium bromide monohydrate.

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19. (previously added) An inhalable powder according to claim 4 comprising 0.2 to 0.5% of tiotropium bromide monohydrate.

20. (previously added) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 20 to 30 µm and finer excipient with an average particle size of 3 to 7 µm.

21. (previously added) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the proportion of finer excipient in the total amount of excipient is 5 to 10%.

22. (previously added) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the tiotropium used has an average particle size of 1 to 6 µm.

23. (previously added) An inhalable powder according to one of claims 1, 2, 3 or 4, wherein the

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tiotropium used has an average particle size of 2 to 5  $\mu\text{m}$ .

24. (previously added) An inhalable powder according to claim 10, wherein lactose monohydrate is used as the excipient.

25. (previously added) An inhalable powder comprising between 0.2 and 0.5% of tiotropium bromide monohydrate in admixture with lactose monohydrate as the physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 20 to 30  $\mu\text{m}$  and finer excipient with an average particle size of 3 to 7  $\mu\text{m}$ , the proportion of the finer excipient constituting 5 to 10% of the total amount of excipient.

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26. (previously added) An inhalette capsule containing from 3 to 10 mg of inhalable powder according to claim 25.

27. (previously added) An inhalette capsule containing from 4 to 6 mg of inhalable powder according to one of claims 1 to 4, 12 or 25.

28. (previously added) An inhalette capsule according to claim 27, containing between 1.6 and 48  $\mu\text{g}$  of tiotropium.

29. (previously added) An inhalette capsule according to claim 27, containing between 2 and 60  $\mu\text{g}$  of tiotropium bromide monohydrate.

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30. (previously added) An inhalette capsule according to claim 27, containing between 4 and 48 µg of tiotropium bromide monohydrate.

31. (previously added) An inhalette capsule according to claim 27, containing between 8 and 30 µg of tiotropium bromide monohydrate.

32. (new) An inhalable powder comprising 0.04 to 0.8% of tiotropium in admixture with a physiologically acceptable excipient, said inhalable powder prepared by a process comprising:  
(a) mixing coarser excipient having an average particle size of 15 to 80 µm and finer excipient having an average particle size of 1 to 9 µm, wherein the proportion of the finer excipient constitutes 1 to 20% of the total amount of excipient, to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium.  
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33. (new) An inhalable powder according to claim 32, wherein the tiotropium is present in the form of the chloride, bromide, iodide, methanesulphonate, para-toluenesulphonate or methyl sulphate thereof.

34. (new) An inhalable powder comprising between 0.048 and 0.96% of tiotropium bromide in admixture with a physiologically acceptable excipient, said inhalable powder prepared by a process comprising: (a) mixing coarser excipient having an average particle size of 15 to 80 µm and finer excipient having an average particle size of 1 to 9 µm, wherein the proportion of the finer

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excipient constitutes 1 to 20% of the total amount of excipient, to obtain an excipient mixture, and

(b) mixing the excipient mixture thus obtained with the tiotropium bromide.

35. (new) An inhalable powder comprising between 0.05 and 1% of tiotropium bromide monohydrate in admixture with a physiologically acceptable excipient, said inhalable powder prepared by a process comprising: (a) mixing coarser excipient having an average particle size of 15 to 80  $\mu\text{m}$  and finer excipient having an average particle size of 1 to 9  $\mu\text{m}$ , wherein the proportion of the finer excipient constitutes 1 to 20% of the total amount of excipient, to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium bromide monohydrate.

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36. (new) An inhalable powder according to claim 35 comprising 0.1 to 0.8% of tiotropium bromide monohydrate.

37. (new) An inhalable powder according to claim 35 comprising 0.2 to 0.5% of tiotropium bromide monohydrate.

38. (new) An inhalable powder according to one of claims 32, 33, 34 or 35, wherein the coarser excipient has an average particle size of 17 to 50  $\mu\text{m}$  and the finer excipient has an average particle size of 2 to 8  $\mu\text{m}$ .

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39. (new) An inhalable powder according to one of claims 32, 33, 34 or 35, wherein the coarser excipient has an average particle size of 20 to 30  $\mu\text{m}$  and the finer excipient has an average particle size of 3 to 7  $\mu\text{m}$ .

40. (new) An inhalable powder according to one of claims 32, 33, 34 or 35, wherein the proportion of finer excipient in the total amount of excipient is 3 to 15%.

41. (new) An inhalable powder according to one of claims 32, 33, 34 or 35, wherein the proportion of finer excipient in the total amount of excipient is 5 to 10%.

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42. (new) An inhalable powder according to one of claims 32, 33, 34 or 35, wherein the tiotropium used has an average particle size of 0.5 to 10  $\mu\text{m}$ .

43. (new) An inhalable powder according to one of claims 32, 33, 34 or 35, wherein the tiotropium used has an average particle size of 1 to 6  $\mu\text{m}$ .

44. (new) An inhalable powder according to one of claims 32, 33, 34 or 35, wherein the tiotropium used has an average particle size of 2 to 5  $\mu\text{m}$ .

45. (new) An inhalable powder according to one of claims 32, 33, 34 or 35, wherein one or more monosaccharides, disaccharides, oligo- or polysaccharides, polyalcohols, salts thereof, or mixtures thereof are used as the excipients.

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46. (new) An inhalable powder according to claim 45, wherein glucose, arabinose, lactose, saccharose, maltose, dextrane, sorbitol, mannitol, xylitol, sodium chloride, calcium carbonate or mixtures thereof are used as the excipients.

47. (new) An inhalable powder according to claim 46, wherein glucose or lactose or mixtures thereof are used as the excipients.

48. (new) An inhalable powder according to claim 47, wherein lactose monohydrate is used as the  
excipient.

49. (new) An inhalable powder comprising between 0.2 and 0.5% of tiotropium bromide monohydrate in admixture with lactose monohydrate as a physiologically acceptable excipient, said inhalable powder prepared by a process comprising: (a) mixing coarser lactose monohydrate excipient having an average particle size of 20 to 30  $\mu\text{m}$  and finer lactose monohydrate excipient having an average particle size of 3 to 7  $\mu\text{m}$ , wherein the proportion of the finer lactose monohydrate excipient constitutes 5 to 10% of the total amount of excipient, to obtain an excipient mixture, and (b) mixing the excipient mixture thus obtained with the tiotropium bromide monohydrate.

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50. (new) A method of treating a disease that is responsive to the administration of tiotropium, comprising administering to a host in need thereof an inhalable powder according to one of claims 32, 33, 34 or 35 or 49.

51. (new) A method according to claim 50, wherein the disease is asthma or COPD.

52. (new) An inhalette capsule containing an inhalable powder according to one of claims 32, 33, 34, 35 or 49.

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53. (new) An inhalette capsule containing from 3 to 10 mg of inhalable powder according to one of claims 32, 33, 34, 35 or 49.

54. (new) An inhalette capsule containing from 4 to 6 mg of inhalable powder according to one of claims 32, 33, 34, 35 or 49.

55. (new) An inhalette capsule according to claim 54, containing between 1.6 and 48 µg of tiotropium.

56. (new) An inhalette capsule according to claim 54, containing between 2 and 60 µg of tiotropium bromide monohydrate.

57. (new) An inhalette capsule according to claim 54, containing between 4 and 48 µg of tiotropium bromide monohydrate.

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58. (new) An inhalette capsule according to claim 54, containing between 8 and 30 µg of tiotropium bromide monohydrate.